

JAN 10 1997

K964138

**Summary of  
Safety and Effectiveness  
Information**

1. Submitter: Varian Oncology Systems  
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- Prepared: October 11, 1996
2. Device Name: Varian Ximatron C-Series Radiation Therapy Simulator  
with Version 4.2 Software
3. Predicate Device: Varian Ximatron C-Series Radiation Therapy Simulator,  
cleared October 28, 1985, 510(k) No. K853349
4. Description: The Varian Ximatron C-Series Radiation Therapy Simulator consists of a stand that supports a gantry and houses various electronic support functions. The gantry houses an x-ray tube housing assembly and supports a collimator and image intensifier with a rotatable cassette holder. Mechanical motions of the Ximatron can be controlled from the control console or hand pendants in the simulator room. The patient couch can also be controlled from side panel controls mounted on the couch.
5. Intended Use: The Ximatron Radiation Therapy Simulator is to be used in radiation therapy simulation, using a fluoroscopic and/or radiographic x-ray system for visualizing the volume to be exposed during radiation therapy and confirming the position and size of the therapeutic irradiation field to be applied.
6. Technological Considerations: The Ximatron simulator reported in this 510(k) is substantially equivalent to the device reported in the prior 510(k). It includes a software controlled feature, Dynamic Motion Management (DMM), which prevents any mechanical part of the Ximatron from colliding with any other part, taking into account a volume, selectable by size, to include the patient. Also included are Delta GoTo, Auto Tracking with Fluoro, and Mouse features.